



DEPARTMENT OF HEALTH & HUMAN SERVICES

MAY 6 2008

Food and Drug Administration
Rockville MD 20857
Re: Zolinza
Docket No.: 2007E-0143

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. RE38506E, filed by Sloan-Kettering Institute for Cancer Research, under 35 U.S.C. section 156 *et seq.* We have reviewed the dates contained in the application and have determined the regulatory review period for Zolinza (vorinostat), the human drug product claimed by the patent.

The total length of the regulatory review period for Zolinza (vorinostat) is 2,449 days. Of this time, 2,266 days occurred during the testing phase and 183 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: January 24, 2000.

The applicant claims October 2, 1999, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 24, 2000, which was the date the IND was removed from clinical hold.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: April 7, 2006.

The applicant claims December 6, 2005, as the date the new drug application (NDA) for Zolinza (NDA 21-991) was initially submitted. However, FDA records indicate that NDA 21-991 was submitted in several modules under the fast track drug development program. It is FDA's position that the approval phase begins when the marketing application is complete for review. The final module of the NDA making it complete for review was submitted on April 7, 2006.

3. The date the application was approved: October 6, 2006.

FDA has verified the applicant's claim that NDA 21-991 was approved on October 6, 2006.

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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,



Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Ivor R. Elrifi, Esq.
Mintz Levin Cohn Ferris Glovsky and Popeo PC
666 Third Avenue - 24th Floor
New York, NY 10017